UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/662,918 | 09/15/2003 | Sean B. Carroll | OPHD-08258 | 2733 |

7590 01/25/2007

MEDLEN & CARROLL, LLP
Suite 350
101 Howard Street
San Francisco, CA 94105

| EXAMINER | |
|---|---|
| KIM, YUNSOO | |
| ART UNIT | PAPER NUMBER |
| 1644 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 01/25/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/662,918 | CARROLL ET AL. | |
| | Examiner | Art Unit | |
| | Yunsoo Kim | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *26 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1 and 3-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/26/06 has been entered.

2. Claims 1 and 3-7 are pending and are under consideration.

3. In view of Applicants' amendment to the claims and arguments, the rejections under 35 U.S.C 112 2nd paragraph and 35 U.S.C 103 (sections 4-6) set forth previously have been withdrawn.

4. The new rejections set forth herein.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out this invention.

6. Claims 1 and 3-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for therapeutic administering of an antibody reactive to *Clostridium perfringens*, does not reasonably provide enablement for a method for prophylactic administering an antibody reactive to *Clostridium perfringens*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification does not enable one of skill in the art to practice the invention as claimed without undue experimentation. Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed.Cir.1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient

working examples, the unpredictability in the art and the amount of experimentation required to enable one of the skilled in the art to practice the claimed invention.

There is insufficient guidance in the specification as filed as to how the skilled artisan would make and use the *Clostridium perfringens* antibody in prophylactic purpose without undue experimentation.

It is known in the art (Arizona Dept. of Health Services, Div. Public Health Service, p. 5.16-5.18) that even though the treatment of the *Clostridium perfringens* is known, there is no preventive measure against *Clostridium perfringens* in food poisoning or in wound infection.

Furthermore, Applicants have no working examples demonstrating *Clostridium perfringens* antibody preventing the disease caused by *Clostridium perfringens* in food poisoning or in wound infection.

To summarize, reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view or the quantity of experimentation necessary, the limited working example, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breath of the claims, it would take undue trials and errors to practice the claimed invention.

7 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1 and 3-7 rejected under 35 U.S.C. 103 as being unpatentable over U.S. Pat. No. 4,748,018 (IDS reference), newly cited, in view of Uemura et al. ( Infection and Immunity, 1974, p. 470-471), newly cited as is evidenced by Merck Manual of Diagnosis and Therapy (17th ed., 1999, p. 1176-1185).

The '018 patent teaches an oral administration of avian antibodies for passively immunizing mammal (abstract, claim 1, col. 6, lines 35-46, in particular). The '018 patent further teaches that the avian antibodies can be made with any antigens or pathogens including *Clostridium tetani* and the like (col. 5, lines 1-35, in particular) and a method provides a therapy for mammals against infectious diseases or conditions caused by an antigen (abstract, col. 7, 42-55, in particular).

In addition, as the '018 patent teaches that the antibody composition can be therapeutically utilized, or as food additives at any feeding stages (col. 9, lines 4-10, in particular), claim 4 which recites infant formula has been included in this rejection

The '018 patent does not teach a particular antigen *Clostridium perfringens* as in claim 1.

As is evidenced by Merck Manual on p. 1176-1185, the most common *Clostridium* infections are caused by *perfringens, tetani or difficile* species. Wound infection, diarrhea and toxic shock are symptoms of clostridial infections and those conditions are treated by similar measures such as antitoxin or antibiotic therapy.

However, Uemura et al. teach *Clostridium perfringens* is a pathogen causing food poisoning as well as gastric diseases (p. 470, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ *Clostridium perfingens* being a pathogen for food poisoning or gastric diseases as taught by Uemura et al. into the therapeutic method and the composition using oral administration of avian antibodies to various antigens including *Clostridium tetani* and the like as taught by the '018 patent.

One of the ordinary skill in the art would have been motivated to do so because the method and the composition comprising administration of an avian antibody to any pathogen including *Clostridium tetani* and the like as taught by the '018 patent provides therapy for conditions or diseases caused by the pathogen. As is evidenced by the Merck Manual, the most common Clostridium infections are caused by *perfringens, tetani or difficile* species and they are treated by the similar measures, the method and the composition taught by the '018 would also provide a therapeutic measure for the pathogen, *Clostridium perfringens* as taught by Uemura et al.

From the teachings of references, it would have been obvious to one of ordinary skill in art would have a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

9. No claims are allowable.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
Patent Examiner
Technology Center 1600
January 12, 2007

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600